



FEB 16 2005

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,153,222

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,153,222, which claims the method of using the human drug product REMODULIN® (treprostinil sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 29, 2004 (69 Fed. Reg. 4306). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,443 - 511) + 583 \\ &= 2049 (5.6 \text{ years})\end{aligned}$$

Since the regulatory review period began May 15, 1991, before the patent issued (October 6, 1992), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 15, 1991 to and including October 6, 1992 is 511 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,153,222


Granted: October 6, 1992

Original Expiration Date¹: October 6, 2009
Applicant: Anjaneyulu S. Tadepalli, et al.
Owner of Record: United Therapeutics, Corp.
Title: Method of Treating Pulmonary Hypertension with
Benzine Prostaglandins
Classification: 514/571
Product Trade Name: REMODULIN® (Treprostinil sodium)
Term Extended: 5 years
Expiration Date: October 6, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents By FAX: (571) 273-7744
Mail Stop Patent Ext. Attn: Office of Patent Legal Administration
P.O. Box 1450
Alexandria, VA 22313-1450

Telephone inquiries related to this determination should be directed to the undersigned at
(571) 272-7744.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: REMODULIN® (Treprostinil sodium)
FDA Docket No.: 03E-0245

¹Subject to the provisions of 35 U.S.C. § 41(b).